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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/616,769

07/10/2003

Yu Momose

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EXAMINER

WANG, SHENGJUN

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

07/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Office Action Summary</p>	<p>Application No.</p> <p align="center">10/616,769</p>	<p>Applicant(s)</p> <p align="center">MOMOSE ET AL.</p>	
	<p>Examiner</p> <p align="center">Shengjun Wang</p>	<p>Art Unit</p> <p align="center">1617</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9,11,15,29,34 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9,11,15,29,34 and 36 is/are rejected.
- 7) ☒ Claim(s) 37,38,43 and 45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____</p> |
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DETAILED ACTION

Receipt of applicants' amendments and remarks submitted April 30, 2007 is acknowledged.

1. The terminal disclaimer filed on April 30 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent 6,605,629 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

2. Claims 37, 38, 43 and 45 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections 35 U.S.C. 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 9, 11, 15, 29, 34, 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating senile dementia of Alzheimer's disease with the compounds herein wherein A is those defined in claim 9, and Y is those defined in claim 11, does not reasonably provide enablement for treating senile dementia of Alzheimer disease with any other compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. The court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

The claims are broadly cover method of treating senile dementia of Alzheimer's disease with compounds defined by the general formula in claim 1, which essentially encompasses unlimited number of compounds with various structurally distinct features. The specification discloses particular compound 1 and 5 have shown excellent NGF and BDNF production/secretion promoting activity. (experimental example 1). The specification provide no working examples, or any rationale that compounds other than those closely related to compounds 1 and 5, i.e. the compounds wherein R1 is amidazolyl group which may optionally be substituted, A is a phenoxy group substituted with an alkyl groups which may optionally be substituted, B is a phenyl group which may optionally be substituted, and Y is divalent

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hydrocarbon group, would be similarly effective as compounds 1 and 5, so that be useful for treating senile dementia of Alzheimer's disease. It is noted that the pharmaceutical art generally is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The court in *In re Fisher*, 427 F.2d 833, 839; 166 USPQ 18, 24 (CCPA 1970) held that, "in case involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." The more unpredictable an area, the more specific enablement is need in order to satisfy the statute. The Unpredictability is more apparent where the diseases disclosed in the specification are as complex and diverse in etiology of Alzheimer's disease. Further, various structural distinct compounds herein deemed to present unpredictability as to their physiological properties. For examples, Compounds with A as C1-4 alkoxy groups are reasonably expected to be different from those with A as phenoxy group. The difference of the sizes, shapes and electronic distribution of the A would certainly affect the physical and chemical properties of the compounds and thereby affects the physiological property. Further, the flexible divalent carbon group as Y certainly has distinct affect compared with heterocyclic group. In the instant case, the art and the evidence presented in the instant application fails to establish support for treatment of senile dementia of Alzheimer's disease with compounds other than those closely related to compounds 1 and 5, i.e. the compounds wherein R1 is amidazolyl group which may optionally be substituted, A is a phenoxy group substituted with an alkyl groups which may optionally be substituted, B is a phenyl group which may optionally be substituted, and Y is divalent hydrocarbon group, as instantly claimed. Thus it would require undue experimentation for the skilled artisan to practice the invention as broadly claimed.

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Response to the Arguments

5. Applicants' amendments and remarks submitted April 30, 2007 have been fully considered, but are not persuasive as to the rejections set forth above. Particularly, there is no rationale that change from a phenoxy groups to an alkoxyl group for A, and/or change from a propyl group to a heterocyclic group for Y in the formula will not affect the therapeutical properties of the oxazole compounds.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Wang
Shengjun Wang
Primary Examiner
Art Unit 1617

SHENGJUN WANG
PRIMARY EXAMINER